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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,826	09/16/2003	Bradford W. Gutting	84554	8902

23501 7590 08/23/2006

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EXAMINER
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MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/666,826	<b>Applicant(s)</b> GUTTING ET AL.	
	<b>Examiner</b> Irene Marx	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 2-9 is/are pending in the application.
- 4a) Of the above claim(s) 1 and 10-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

The amendment filed 7/17/06 is acknowledged. Claims 2-9 are being considered on the merits.

Claims 1 and 10-20 are withdrawn from consideration as directed to a non-elected invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ireland *et al.* taken with ATCC Catalogue and Citri for the reasons as stated in the last Office action and the further reasons below.

The claims are directed broadly to a process of making a germinant by providing macrophages IC-21 and adding spores. In dependent claims the germinant is filtered.

Ireland *et al.* teach a process of making a germinant by providing macrophages and adding spores. The step of adding spores occurs at 10:1 macrophages to spores, for example. See, e.g., Figure 1. That a suitable germinant is produced is evidenced by germination efficiency (Table 3), particularly for spores of *B. anthracis*.

The reference differs from the invention as claimed in that the macrophages are not IC-21. However, the ATCC Catalogue adequately demonstrates that this particular cell line is old and well known in the art. In addition, Citri discloses that various germinants for spore-formers such as *Bacillus* strains are known in the art, such as inosine, glucose, L-alanine, L-proline, etc. See, e.g., Table 2.

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One of ordinary skill in the art would reasonably have expected that substitution of a substantially similar cell lines similarly derived from macrophage result in the of a germinant for a spore producing microorganism such as *Bacillus*, particularly since suitable germinants are known to be available in culture media.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Ireland *et al.* of producing a germinant with a macrophage cell line and spores by replacing the macrophages of Ireland with IC-21 macrophages as suggested by the teachings of the ATCC Catalogue and Citri for the expected benefit of obtaining a suitable germinant for the effective and rapid detection of pathogenic or deleterious spore-producing microorganisms.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

#### **Response to Arguments**

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. In *re* Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In *re* Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Ireland *et al.* reference adequately demonstrates that a process of making a germinant by providing macrophages and adding spores is old and well known in the art. The reference teaches the use of other macrophage cultures, while the ATCC Catalogue adequately demonstrates that the particular cell line IC-21 is old and well know in the art. Inasmuch as the production of germinants using macrophages is know, one of ordinary skill in the art would have reasonably expected that the substitution of one type of culture for another for provide similar results of providing a germinant.

Applicant's basis for the bald assertion that the article and the specification are objective evidence that macrophages would not be expected to react similarly in the presence of

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endospores is unclear. The relevance of the susceptibility to macrophages to endospores in the context of the instant invention is also unclear. The test results in the attached reference are directed to a specific strain of *Bacillus anthracis* Vollum 1B (VIB) cultured in specific macrophage cultures and its effects on macrophages are provided. No germinants appears to be produced. The claims are directed to the production of a germinant without indication as to the nature of the germinant produced.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in cursive script, appearing to read "Irene Marx".

Irene Marx  
Primary Examiner  
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